# NEO Total Knee System – Line Extension
# 510(k) Summary

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| **Device Proprietary Name:** | NEO Total Knee System |
| **Common Name:** | Artificial Total Knee System |
| **Classification regulation:** | 888.3560 - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis |
| **Device Class:** | Class II |
| **Product Codes:** | JWH (cemented knees) |


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| **Submitter's Name:** | Pipeline Orthopedics |
| **Address:** | 3 Wing Drive, Suite 102<br>Cedar Knolls, NJ 07927 |
| **Contact Person:** | Robert C. Cohen |
| **Telephone Number:** | (973) 267-8800 |
| **Fax Number:** | (973) 267-8810 |


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| **Date Summary Prepared:** | May 10, 2013 |

**Device Description:**
The NEO Total Knee System was cleared for marketing in April 2012, under 510(k) #K120313. The predicate knee system includes a cruciate retaining (CR) femoral component design, tibial trays, CR tibial inserts for use with intact posterior cruciate ligament(PCL), and patellar components. The subject 510(k) adds ultra congruent (UC) tibial inserts for use when the PCL is sacrificed. There are no changes to materials or to system component size offering.

The Neo Knee System CR femoral components, when used with the mating Neo Knee System CR and UC articular surfaces, are designed to achieve flexion at high angles and provide a clinical ROM up to 150 degrees.

**Intended Use**
The NEO Total Knee System components are indicated for use in skeletally mature individuals, with severe knee pain and disability, undergoing surgery for total knee replacement due to:

- Osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, moderate deformities and femoral condyle osteonecrosis.
- Failed osteotomies, failed partial knee replacement, or failed total knee replacement whose age, weight and activity level are compatible with an adequate long-term result.

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- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate valgus, varus, or flexion deformities.

The Neo Total Knee System components are indicated for use only with cement and are single use devices.

**Predicate Devices:**
The NEO Total Knee System is similar to several predicates including the following.

| Trade/Proprietary Name | Manufacturer | 510(K) # | Clearance Date |
|---|---|---|---|
| Neo CR Total Knee | Pipeline Orthopedics | K120313 | 04/20/2012 |
| Triathlon Knee System, CS (condylar stabilizing) tibial inserts | Stryker Orthopaedics (Stryker Howmedica Osteonics) | K063423 | 01/22/2007 |
| Journey II Deep Dished Articular Inserts | Smith & Nephew Orthopaedics | K113482 | 02/27/2012 |

**Purpose of Submission:**
The 510(k) submission includes a line extension that adds ultra congruent (UC) tibial inserts to the predicate Neo Total Knee System.

**Technological Characteristics:**
The metal and the standard UHMWPE material from which the components are manufactured are the same materials used in the predicate Neo Total Knee System and comply with applicable implantable materials standards. A comparison of design features of the subject to the predicate knee systems and performance testing confirm that the subject NEO Total Knee System is capable of withstanding the anticipated physiological conditions associated with the indications for use and is substantially equivalent to the predicate devices.

**Performance Testing:**
The NEO Total Knee System has been evaluated, either by new testing submitted in this 510(k) or by testing previously submitted in predicate 510(k) #K120313, for tibial tray fatigue strength, insert locking mechanism strength, femorotibial range of motion, femorotibial range of constraint, patellofemoral range of constraint, femorotibial contact areas/contact stress, patellofemoral contact area and contact stress, and characterization of the UHMWPE. The testing confirms that the NEO Total Knee System, including the subject UC inserts and the compatible predicate femoral components, tibial trays, and patellar components (510(k) #K120313), is capable of withstanding

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expected in vivo loading and is substantially equivalent to competitive legally marketed knee systems.

**Conclusions:**

The NEO Total Knee System shares the same indications for use and materials and manufacturing methods as the predicate Neo CR Knee System, and is similar in design and technological and performance characteristics to one or more of the cited predicate devices. The NEO Total Knee System is therefore substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

Pipeline Orthopedics
% Ms. Terry Powell
M Squared Associates, Incorporated
901 King Street
Suite 102
Alexandria, Virginia 22314

Re: K131368
Trade/Device Name: NEO Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: August 13, 2013
Received: August 14, 2013

Dear Ms. Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

**510(k) Number:** ~~To be assigned~~ K131368

**Device Name:** NEO Total Knee System

**Indications for Use:**

The NEO Total Knee System components are indicated for use in skeletally mature individuals, with severe knee pain and disability, undergoing surgery for total knee replacement due to:

- Osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, moderate deformities and femoral condyle osteonecrosis.
- Failed osteotomies, failed partial knee replacement, or failed total knee replacement whose age, weight and activity level are compatible with an adequate long-term result.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate valgus, varus, or flexion deformities.

The Neo Total Knee System components are indicated for use only with cement and are single use devices.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices